K062757

510(k) SUMMARY

NOV - 7 2006

General Information

Submitted by:	XERON Healthcare Corp. A-206 Hi-Tech Venture Center, 647-26 Deungchon-Dong, Gangseo-Gu Seoul, Korea Phone: +82 2 3663 8424 Fax: +82 2 3663 8426
Contact Person:	Mr. Douglas Kim A-206 Hi-Tech Venture Center, 647-26 Deungchon-Dong, Gangseo-Gu Seoul, Korea Phone: +82 2 3663 8424 Fax: +82 2 3663 8426 Email: douglas_kim@xeron.co.kr
Date Prepared:	September 11, 2006

Device Name

Trade Name:	Xeron PACS
Common Name:	Picture Archiving and Communications System
Classification Name:	System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
GE Medical Systems Information Technologies	GE Centricity PACS	K043415

Device Description

Xeron PACS is an image management system that allows authorized personnel to acquire, display, edit, review, store, print, and distribute standard Digital Imaging and Communications in Medicine (DICOM) medical images within a Picture Archiving and Communication System (PACS) environment. The Xeron PACS system consists of five software components:

- XP WebStation
- XP RadStation
- XP Site Administrator
- XP Data Router
- XP Server Manager

Xeron PACS supports DICOM network structures which allow for efficient medical image acquisition from any medical modality, including CT, MR, CR, and others. Distribution of images is provided to desktop computer systems, computer systems connected by intranet or internet, hardcopy devices, and Hospital Information Systems (HIS).

Intended Use

The Xeron PACS is a medical imaging software application intended to display, edit, review, store, print and distribute images acquired from imaging devices such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Ultrasound (US), Nuclear Medicine (NM), and other devices.

Technological Comparison

Xeron PACS and GE Centricity PACS are software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

Xeron PACS has been demonstrated to perform as intended.

Conclusions

Xeron PACS is substantially equivalent to legally marketed Image Processing Systems (i.e. PACS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

XERON Healthcare Corp.
% Mrs. Melissa Mahall
Director, Regulatory Affairs
Bio-Reg Associates, Inc.
6304 Belmont Circle, Bldg 2
MOUNT AIRY MD 21771

NOV - 7 2006

Re: K062757
Trade/Device Name: Xeron PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 11, 2006
Received: September 20, 2006

Dear Mrs. Mahall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062757

Device Name: Xeron PACS

Sponsor Name: XERON Healthcare Corp.

Indications for Use:

The Xeron PACS is a medical imaging software application intended to display, edit, review, store, print and distribute images acquired from imaging devices such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Ultrasound (US), Nuclear Medicine (NM), and other devices.

Prescription Use ☒ (21 CFR 801 Subpart D)

Or

Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062757